Section 6

FEB 0 7 2003

Silicone Dual Lumen RadPICC Catheter

510(k) Summary of Safety and Effectiveness Information
21 CFR 807.92

1. Submitter Information

Submitter Name:	Bard Access Systems, Inc. (Subsidiary of C.R. Bard, Inc.)
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 4903
Fax Number:	(801) 595-5425
Contact Person:	Peggy Keiffer
Date of Preparation:	December 27, 2002

2. Device Name

Device Name:	Silicone Dual Lumen RadPICC® Catheter
Trade Name:	RadPICC® Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter 21 CFR 880.5970
Classification Panel:	General Hospital

3 Predicate Device Name:

Device Name:	Per-Q-Cath and Per-Q-Cath Dual Lumen PICC Catheter
Trade Name:	Per-Q-Cath and Per-Q-Cath Dual Lumen Catheter, Trays and accessory devices
Common/Usual Name:	Peripherally Inserted Central Venous Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital

6. Device Description

The device description of the subject Silicone Dual Lumen RadPICC Catheter is as follows:

- The RadPICC® catheters are open-ended dual lumen catheters that are made of soft silicone elastomer containing barium sulfate throughout the tubing for enhanced radiopacity.
- The RadPICC® catheters are 5, 6 Fr dual lumen x 60 cm usable length. The catheter lumens are non-symmetrical rounded D shape for maximized flow and mechanical properties.
- The proximal end of the RadPICC catheters consists of two luer lock connectors, glued compression sleeves, clear silicone extension legs for visibility during use and non-removable mini thumb clamps. The extension legs are pre-printed with the lumen gauge size. The extension legs are molded into the bifurcation. StatLock® compatible suture wings are molded into the bifurcation to facilitate easy, secure placement. The bifurcation is embossed with identification text.

- The proximal end of the catheter tubing has a stepped strain relief that minimizes the potential for kinking at the catheter tubing / strain relief interface. The tubing is pre-molded into the bifurcation with a "0" mark that serves as a reference for the catheter insertion point. The catheter can be inserted up to the "0" mark, which is sized to the exit site, thereby allowing the clinician to "plug" the insertion site.
- The catheter tubing has depth markings in centimeter increments originating from the proximal end and running the full length of the catheter.
- A stand-along hydrophilic stylet is provided as a kit components and is loaded by the clinician during the placement procedure.
- Catheters are provided sterile with kit components preferred by interventional radiologists.

5. Intended Use and Indication for Use

The intended use of the Silicone Dual Lumen RadPICC Catheter is to provide venous access to infuse intravenous medication, nutritional therapy, or blood therapy.

The Indications for use is: *The silicone RadPICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For blood therapy, utilize the larger lumen.*

6. Technological Characteristics Summary:

6.1 Does the new device have the same indication statement?

Yes, with minor modification.

6.2 Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The Silicone RadPICC catheters have some minor differences from the predicate Per-Q-Cath PICC catheters. However, the basic fundamental scientific technology of the catheter has not changed.

6.3 Could the new characteristics affect safety or effectiveness?

Yes. The integrity of the minor design changes and materials could affect the safety or effectiveness of the device.

6.4 Do accepted characteristics raise new types of safety and effectiveness questions?

No. There are no new issues of safety and effectiveness.

6.5 Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters", dated 3/16/95, and corresponding ISO Standards were used to evaluate the device's performance.

Biocompatibility meets the requirements of ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and the FDA Modified ISO 10993 Test Profile for externally communicating blood contacting long term devices.

6.6 Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed according to the above referenced guidance and standards. The results met the requirements and were similar to the predicate device.

6.7 Are performance data available to assess effects of new characteristics?

Yes. Performance data demonstrate that the silicone dual lumen RadPICC Catheter is substantially equivalent to the predicate Per-Q-Cath PICC Catheter, K954104.

6.8 Performance Data (if applicable).

The following Catheter guidance tests were performed in accordance with "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters", dated 3/16/95:

- Dimensions
- Flow rate
- Tensile:
  Tensile strength of catheter body
  Tensile strength of extension leg to hub attachment (luer connector)
  Tensile strength of extension leg to bifurcation
- Tensile strength of bifurcation to catheter body
- Catheter stiffness (modulus)
- Catheter elongation
- Leak:
  Leakage at hub
  Leak at hub with burst
  Catheter assembly leak
- Catheter burst pressure:
  Assembly
  Extension leg
  Extension leg after clamping
  Catheter shaft tubing
- Catheter collapse
- Catheter flexural fatigue tolerance
- Priming volume
- Radiopacity
- Biocompatibility

The following additional tests were performed:

- Creep
- Stylet withdrawal force
- Kink resulting in decreased flow

The following catheter guidance tests were NOT required for this product change:

- Catheter tip (distal) attachment strength (there is no tip attachment)

6.9 Conclusion

The Silicone RadPICC catheters met all the predetermined performance criteria of design verification. Based on FDA's decision tree, the silicone RadPICC catheters are substantially equivalent to the predicate device, the Per-Q-Cath PICC catheters, K954104, concurrence date November 21, 1995.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 07 2003

C.R. Bard, Incorporated
Ms. Peggy Keiffer
Senior Regulatory Affairs Manager
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K030255
Trade/Device Name: Silicone Dual Lumen RadPICC® Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous Implanted, Long-term IntravascularCatheter
Regulatory Class: II
Product Code: LJS
Dated: January 23, 2003
Received: January 24, 2003

Dear Ms. Keiffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1.2

Silicone Dual Lumen RadPICC® Catheter 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Manager of Bard Access Systems, that this notification [510(k)] for the following devices, Silicone Dual Lumen RadPICC Catheters, are indicated for the following:

> The RadPICCs are indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For blood therapy, utilize the larger lumen.

Signature of 510(k) Submitter: Peggy Keiffer

Printed Name of Submitter: Peggy Keiffer

Date: 1.9.03

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number K030255

Division Sign-Off
Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030255

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